

REMARKS

Applicant has carefully studied the outstanding Official Action mailed on October 30, 2006. This response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

Applicants wish to express their gratitude to Examiner Nguyen and Supervisor Hindenburg for the courtesy of a telephone interview with their representative David Klein, Registered Patent Agent 41118, on May 7, 2007.

In the interview, language of claim 1 was discussed and the language has now been amended in this supplemental amendment to make the claimed invention even clearer. The amended language is taken from the last paragraph on page 4: "The position sensors 24 may be placed near the EMG sensors 30 and 36, such that position sensing system 22 may measure the three-dimensional position of EMG sensors 30 and 36. Processor 18 may then process the electrical muscular activity signals as a function of their three-dimensional positions and as a function of the CTG monitor 12 readings at the same time." No new matter has been introduced.

The drawing of Fig. 2 stands objected under 37 CFR §1.83(a) for failing to "clearly show the 3D image of muscle contraction as sensed by the claimed position sensing system." Examiner states "it is still not understood how '44' shows a three-dimensional image of muscle contraction".

Applicant respectfully wishes to point out that the commonly accepted drawing standard to depict movement is to show wavy lines next to the object that moves. This is the commonly accepted drawing standard for patent drawings and virtually all kinds of drawings. Fig. 2 clearly shows wavy lines both in the uterine muscle and next to it. It is thus clear that Fig. 2 shows movement of the uterine muscle, which in other words is the 3D image of muscle contraction. Thus the objection is respectfully traversed and considered overcome.

Claim 6 stands rejected under 35 USC §112, first paragraph (and second paragraph for basically the same reason) for failing "to describe or teach one of ordinary skill of the art how the claimed processor [is] operative to process data of the claimed EMG system and the claimed three-dimensional position and orientation information from the at least one position sensor [to] provide an output that comprises electromyographic activity data as a function of the three-dimensional position and orientation of said at least one position sensor."

Applicant respectfully traverses the 112 rejections. However, in order to expedite allowance of this application, claim 6 has been amended along the lines of claim 1.

Claims 1-3, 5-7 stand rejected under 35 USC §103(a) as being unpatentable by Garfield et al. (US 6816744) in view of Krausman et al. (US 6095991).

Claim 4 stands rejected under 35 USC §103(a) as being unpatentable by Garfield et al. (US 6816744) in view of Krausman et al. (US 6095991), further in view of Triano (US 5991701).

Applicant respectfully traverses these rejections and maintains that these rejections are not proper under 35 USC §103(a).

The basic considerations that apply to obviousness rejections under MPEP §2141 are as follows:

- a) the claimed invention must be considered as a whole;
- b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- c) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- d) reasonable expectation of success is the standard by which obviousness is determined.

When the prior art itself fails to meet **even one** of the above criteria the cited art does not satisfy 35 USC §103(a) and prevents the establishment of the required *prima facie* case of obviousness by the Examiner. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also In re Rijckaert, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Moreover, to establish the required case of *prima facie* obviousness, the Examiner is required to demonstrate that the prior art discloses or suggests all the critical elements of the invention, without reference to applicants' specification, and that the existence of these elements enables one skilled in the art to practice the invention. See In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991).

Moreover, if the prior art methodology must be modified in any way to practice the instant invention the prior art citation must *also* render obvious these modifications or provide a reasonable expectation for the successful practice of the invention with the necessary modifications.

In point 13 of the OA, the Examiner says that the EMG system of Garfield et al. can be combined with the position sensor of Krausman et al. because "it would be obvious...to use a position sensor as disclosed by Krausman et al. in conjunction with another medical

monitoring instrument such as the EMG system of Garfield et al. to allow better monitoring of electromyographic activity.”

The Examiner, in point 14, says that Garfield et al. discloses “determining the position of electrical muscular activity signals (col. 29, lines 50-61).”

This is respectfully traversed. First, regarding point 13, Examiner is referring to Kaufman et al. col. 8, lines 22-27: “A further application of the present invention would be to integrate the positional and motion detecting properties of the device with other monitoring instruments, such as oximeters, apnea monitors, respiration monitors, airflow monitors, heart rate monitors, activity and other types of medical monitors for the purposes of gaining a better understanding of the physiological function being measured. For example, the position and motion of the subject’s body, head or limbs could provide valuable qualitative information for the rejection of artifacts (e.g., false oximeter indicated periods of breathing abnormalities in sleep apnea studies) and a more accurate assessment of the physiological function being monitored.”

The only thing that Kaufman et al. teaches in integrating “the positional and motion detecting properties of the device” with a heart rate monitor is simply to “gain a better understanding of the physiological function being measured”. Kaufman et al. explains this means to obtain “valuable qualitative information” “and a more accurate assessment of the physiological function being monitored”.

In other words, Kaufman et al. teaches using the position sensor to make sure the data of the physiological sensor is providing good quality data. This means (in the example quoted above from the text of Kaufman et al.) that in the case of an oximeter indicating a breathing abnormality, the position sensor will sense the breathing motion of the person to see if there really is some abnormal breathing. By inference, this means in the case of a heart monitor the position sensor will sense the chest motion of the person to see if there really is some abnormal heart beats. However, Kaufman et al. is silent about utilizing the position sensor to provide an **output and display** of said electrical muscular activity signals and their three-dimensional positions **at the same time**. Nowhere does Kaufman et al. describe or show an **output and display** of any kind of electrical muscular activity signals and their three-dimensional positions **at the same time**.

Accordingly, there is absolutely no teaching or explanation whatsoever of how to combine Kaufman et al. with an EMG system to do the claimed invention, namely, how “to process electrical muscular activity signals of said EMG system and three-dimensional positions of said electrical muscular activity signals from said at least one position sensor to

provide an output and display of said electrical muscular activity signals and their three-dimensional positions at the same time”. In light of the abovementioned basic considerations that apply to obviousness rejections under MPEP §2141, it is respectfully submitted that it is insufficient to simply combine the position sensor of Krausman et al. with the EMG system of Garfield et al. and to arrive at the claimed invention. The Examiner must show exactly where in the text of the references is there teaching how to do this. The Examiner has not done this, and respectfully it is submitted that no one can, because no such teaching exist in the references. No motive or incentive is found in the references to arrive at the claimed invention. In short, a combination that purportedly provides “better monitoring of electromyographic activity” does not make obvious nor anticipate “a processor operative to process electrical muscular activity signals of said EMG system and three-dimensional positions of said electrical muscular activity signals from said at least one position sensor to provide an output and display of said electrical muscular activity signals and their three-dimensional positions at the same time.”

Regarding point 14 of the OA, the quoted passage from Garfield et al. that purportedly discloses “determining the position of electrical muscular activity signals (col. 29, lines 50-61) is as follows: “The results can be displayed on-screen or may be printed on a printer. Using this method the **vector of activity** can be defined, and the origin and spread of activity may also be defined. Further, pacemaker regions and **direction of propagation of uterine electrical activity** may be identified. These parameters may then be used to characterize women as labor or non-labor, may assist with predicting necessary treatments of pregnant women, or facilitate making other obstetrical diagnoses. In the present invention, a similar treatment also using **vector analysis** can be performed to monitor and/or characterize the maternal and fetal cardiac electrical activity as well as fetal brain activity.” It is noted that the vector references are described in Garfield et al. in col. 29, line 25-26.

This rejection based on Garfield et al. is respectfully traversed. It will now be carefully explained that Garfield et al. is talking about vector components and directions of **the potential**. This has nothing to do with position and spatial information.

First, the only place Garfield et al. explains using three dimensions is a three-dimensional mesh mentioned in claim 31: “The method of claim 1, further comprising generating three dimensional mesh plots of said power density spectral characteristics, said mesh plots displaying energy levels versus frequency versus time of pregnancy”. Thus it is clear that the three dimensions are **not** spatial dimensions but rather energy, frequency and time.

Furthermore, the three-dimensional vector tracings of Garfield et al. have nothing to do with positional information provided by a position sensor. A position sensor tells where an object is in space, e.g., the object is found at Cartesian coordinates $x=1.25$, $y=2.5$, $z=-0.7$. The three-dimensional vector tracings are not spatial coordinates, rather the x , y , z **components** of the vector, i.e., the vector points in a direction with a magnitude. The three-dimensional vector tracings are simply the x -component, y -component and z -component of a *body surface potential* vector, i.e., how much potential points in the x -direction, how much in the y -direction, etc. Attention is respectfully drawn to the passages previously cited by the Examiner in Garfield et al. regarding the vector:

“A. General Principles

Body surface potential vector analysis is based on Frank's torso experiment model and research results...From measurements in such experiments, Frank found that the geometrical transfer coefficients that relate the dipole source to each point of the body surface potential $V_n(t)$. Thus for a set of k body surface potentials, there is a set of k equations that can be expressed in matrix form...Based upon this dipole analysis, and making the dipole source a uterus of a pregnant women, the potential at any point and at the same time can be measured to obtain the orthogonal vector component of the action potentials on an XYZ axis. An example of the placement of electrodes on a patient, and a 3-dimensional position of electrodes located on an XYZ axis is shown in FIGS. 12A, 12B, and 12C below. When acquiring the six-point potential at any time, the vector component on X, Y axis at this time is also obtained. It is noted that the direction is that the vector points toward the electrode with higher potential. For example, if $P_x > 0$, then the direction is in X positive direction.” Garfield et al. also talks about “determining potential vector characteristics of the signals to identify direction and rate of propagation of uterine electrical activity”.

It is clear that Garfield et al. is talking about vector components and directions of the potential. This has nothing to do with position and spatial information. This has nothing to do with the claimed invention and has nothing to do with sensing position. Where does Krausman et al. show or teach how to measure the three-dimensional positions of “energy levels versus frequency versus time of pregnancy”? The answer is nowhere. Moreover, since Krausman et al. does not contemplate measuring this, then of course Krausman et al. does not contemplate displaying the three-dimensional positions of “energy levels versus frequency versus time of pregnancy”. The Examiner cannot combine references without specifically showing how the references teach producing the claimed invention, that is, to

show how to combine the position sensor of Krausman et al. with the system of Garfield et al. “to provide an output and display of said electrical muscular activity signals and their three-dimensional positions at the same time” as is claimed in claim 1 of the instant invention. This has not been done, and indeed cannot be done, because the references do not contemplate this.

Examiner states in point 16 that Garfield et al. teaches “display of more than one type of data at the same time, as exemplified in Figure 3 (col. 14, lines 62-67)”.

Quoting from the text it says: “FIG. 3 displays three plots: a plot (30), generated by processing trans-abdominal uterine EMG signals with spectral-temporal mapping as one method in accordance with the present invention; a simultaneously-recorded corresponding plot (31), generated by a standard tocodynamometer; and a plot (32), the raw EMG signal used to generate the processed EMG plot. The high degree of correspondence of plot 30 to plot 31 is grounds for using the present invention as a replacement to the tocodynamometer.” Firstly, Fig. 3 does not display the electrical muscular activity signals and their three-dimensional positions at the same time, and this is not taught by combining Garfield et al with Krausman et al as explained above. Secondly, the method of Garfield et al. does not even teach displaying EMG signals together with TOCO signals. Rather the two graphs 30 and 31 were merely presented together in Fig. 3 for comparison purposes to show that Garfield et al can supposedly replace the prior art (“The high degree of correspondence of plot 30 to plot 31 is grounds for using the present invention as a replacement to the tocodynamometer”), but that does not mean that Garfield et al contemplate displaying EMG signals together with TOCO signals in their idea for an invention.

The Examiner cannot combine references without specifically showing how the references teach producing the claimed invention, that is, to show how to combine the position sensor of Krausman et al. with the system of Garfield et al. “to provide an output and display of said electrical muscular activity signals and their three-dimensional positions at the same time” as is claimed in claim 1 of the instant invention. This has not been done, and indeed cannot be done, because the references do not contemplate this. Accordingly, claims 1-7 are deemed allowable.

Application No. 10/616,995

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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